

REMARKS

Section 112 rejections:

Claims 25 and 26 are canceled and the limitations inserted into claim 7 to limit claim 7 as amended and inserted into claim 28 newly presented. The term "therapy balloon" has been restricted to either an angioplasty balloon in claim 7 and a stent deployment balloon in claim 28. These amendments clarify the intended scope of the claims to cover obdurator type therapy balloons.

102 arguments

The elected species of the Applicant's invention is the method of clearing debris using a catheter assembly. The assembly has two parts. A **PTCA angioplasty device** with a fluid delivery nozzle distal of the balloon and a **Sheath** with a discharge lumen. The sheath is not sealed against the vessel and the discharge lumen may or may not provide suction.

The cited references are all directed to the same problem addressed by the applicant. However Neracher '482, Simpson '529 and Cabo '060 all have a balloon mounted on the sheath to occlude the vessel during the procedure. See item 14 in Neracher, see item 48 in Simpson and item 44 in Carbo. Applicants' amended claims exclude a proximal balloon on the sheath and this is one reason that the amended Claims are not anticipated by Neracher, Simpson and Carbo.

Nash on the other hand also lacks the proximal occlusion balloon and shares this distinction with the applicant's device. For that reason Applicants admit that this distinction is not enough to overcome that reference alone. However the applicants' broadest claims also restrict the therapy delivered to balloon angioplasty or stent deployment. Nash '170 does not show balloon angioplasty or stent deployment and the therapies have been restricted in the claims to one of these two therapies. So in conclusion Applicants' submit that none of the references show the fundamental combination of 1) a sheath without an occlusion balloon and having a discharge lumen cooperating with 2.) a balloon therapy catheter that delivers fluid distal of the therapy balloon. 3.) where the debris is removed via the discharge lumen. Applicant admits that parts of his combination can be found in the references in different combinations but no single references has all the elements called for by the broadest amended claims. Any

single reference standing alone is missing one or more elements of Applicants' broadest claims.

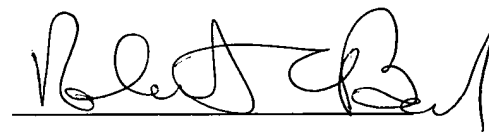
103 arguments

The Examiner has argued that either Nash '170 or Simpson '529 teaches the basic combination and that using a syringe or other device to inject and extract is known in the art. The amended claims require that fluid be injected distal of a PTCA or stent deployment balloon in conjunction with the therapy. However the fundamental teaching of the applied references is to isolate and stop flow in the vessel with a balloon distal in the case Nash and both proximal and distal in the case of Simpson. Next these references teach an intervention with a cutter therapy. The references do not teach stent deployment or balloon angioplasty with a fluid injection port distal to the therapy section on a catheter. Applicant s' submits that the claimed invention set forth in the now amended claims is not obvious.

Applicant notes that Nash does not appear to be prior art to applicant based on earliest filing date but treats the reference as prior art since applicant believes other references are equivalent with respect to the rejection and this argument.

Respectfully submitted,
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Version Showing Changes

7. A method of removing particulate debris from a vessel using a catheter assembly the method comprising:

inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel; said sheath partially blocking the vessel but allowing some blood flow in the vessel;

inserting and advancing an interventional device to a treatment location, said interventional device of type having;

an angioplasty therapy balloon for delivering angioplasty treatment;

a gap for introducing a primary fluid flow in said vessel, said gap located distal of said therapy balloon;

injecting fluid out of said gap to promote retrograde flow into said discharge lumen.

8. The method of claim 18 wherein said moving step begins near said occlusion and ends after the interventional device enters the delivery sheath.

9. The method of claim 7 wherein said fluid is injected at a first injection pressure above the blood pressure in the vessel and expands to a second exhaust pressure in said delivery catheter where said exhaust pressure is above said blood pressure, establishing a pressure gradient in said discharge lumen and promoting flow from said gap to said discharge lumen.

18. The method of claim 7 wherein said injection is carried out while moving said interventional device in said vessel with respect to said delivery sheath.

19. The method of claim 7 wherein said discharge lumen is coupled to a syringe collection chamber.

20. The method of claim 7 wherein said discharge lumen is coupled to a syringe vacuum chamber.

21. The method of claim 7 wherein said primary fluid is supplied by a supply syringe chamber.

22. The method of claim 21 wherein the fluid supplied is a thrombolytic.

23. The method of claim 21 wherein the fluid supplied is saline.

24. The method of claim 21 wherein the fluid supplied is contrast agent.

25. —~~The~~(cancelled) The method of claim 7 wherein the therapy balloon provides angioplasty therapy.

26. —~~The~~26.(cancelled) The method of claim 7 wherein the therapy balloon provides stent placement therapy.

27. The method of claim 7 wherein said primary fluid is supplied by a supply syringe chamber and said discharge lumen is coupled to a syringe vacuum chamber, and said supply syringe and vacuum syringe are operated together to couple fluid supply with discharge lumen collection.

28 new. A method of removing particulate debris from a vessel using a catheter assembly the method comprising:

inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel; said sheath partially blocking the vessel but allowing some blood flow in the vessel;

inserting and advancing an interventional device to a treatment location, said interventional device of type having;

a stent deployment therapy balloon for delivering stent treatment;

a gap for introducing a primary fluid flow in said vessel, said gap located distal of said therapy balloon;

injecting fluid out of said gap to promote retrograde flow into said discharge lumen.

30. (new) The method of claim 7 further including a suction applied to said sheath lumen to withdraw material form said vessel.

31. (new) The method of claim 29 further including a suction applied to said sheath lumen to withdraw material form said vessel.

Clean Version of Replacement Claims

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an angioplasty therapy balloon for delivering angioplasty treatment;

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8. The method of claim 18 wherein said moving step begins near said occlusion and ends after the interventional device enters the delivery sheath.

9. The method of claim 7 wherein said fluid is injected at a first injection pressure above the blood pressure in the vessel and expands to a second exhaust pressure in said delivery catheter where said exhaust pressure is above said blood pressure, establishing a pressure gradient in said discharge lumen and promoting flow from said gap to said discharge lumen.

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26. (cancelled) The method of claim 7 wherein the therapy balloon provides stent placement therapy.

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B³ inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel; said sheath partially blocking the vessel but allowing some blood flow in the vessel;

inserting and advancing an interventional device to a treatment location, said interventional device of type having;

a stent deployment therapy balloon for delivering stent treatment;

a gap for introducing a primary fluid flow in said vessel, said gap located distal of said therapy balloon;

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30. (new) The method of claim 7 further including a suction applied to said sheath lumen to withdraw material form said vessel.

13 31. (new) The method of claim 29 further including a suction applied to said sheath lumen to withdraw material form said vessel.